Medical Devices for Sleep Diagnostics and Therapy
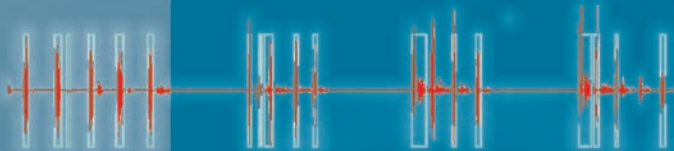
SOMNOmedics

SOMNOwatch®
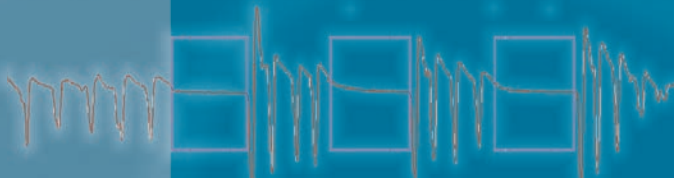
- **MINIMUM EFFORT**
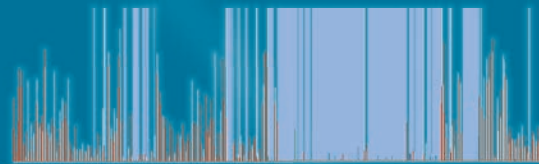- **OPTIMUM DIAGNOSTICS**
- **FLEXIBLE APPLICATION**

**Respiration
(Flow and Snore)**

Actigraphy
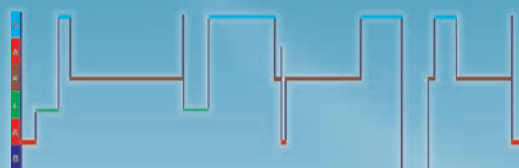
Tremor Analysis 3D

SOMNOwatch plus®

SOMNO medics

**Sleep Profile
(Wake, REM, 1, 2, 3, 4)**

PLM-Recorder

Long-term ECG Recording

Body Position

The All-rounder

FDA approved for adults only

SOMNOwatch®

Ambulatory Multi-Channel Monitoring

Miniaturised - Mobile - Flexible

The rapid progression in electronics has lead to a general miniaturisation in Mobile Medical Devices. The integration of multiple diagnostic functions into one single device allows for a flexible and cost effective system. **SOMNOwatch**® is a powerful miniaturised multi channel recorder which includes the comfort and user friendliness of a watch.

As a multi-channel system, the **SOMNOwatch**® can replace several common devices while providing excellent signal quality. **SOMNOwatch**® can be used for **Actigraphy** in order to determine Circadian Rhythm, **PLM detection**, **Tremor Analysis**, **Single Channel ECG** and **EEG recording**, **Body Temperature**, **Respiratory Screening** with Flow & Snoring, Body Position, and **Sleep/Wake Analysis**. The waterproof device is powered by a rechargeable Li-Ion battery and has an internal storage of 8/16 MB enabling long-term measurements of up to 26 days. Relevant points in time on the recording can easily be marked with the integrated Patient Marker.

Actigraphy

Circadian Rhythm - SOMNOwatch® is worn on the non-dominant arm for recording and objective recognition of the Sleep/Wake Rhythm. The activity is measured in epochs of 1 to 120 seconds and plotted as an Actigraphy Profile. The relevant measurement period (time in bed) is given using the integrated Light Sensor. As a result, disorders of the Circadian Rhythm e.g. for shift workers or pilots, can be documented. In Attention Deficit and Hyperactivity Disorder (ADHD), **SOMNOwatch**® can be used to diagnose and monitor the therapy of hyperactive children. Certain periods can be assigned to specific events, such as School, School Breaks and leisure time.
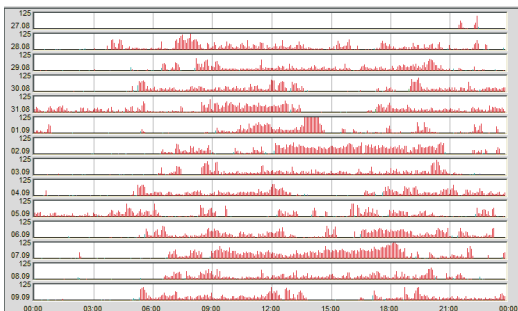

FDA approved for adults only

Exercise/Sport/Rehabilitation - To get important Motor Activity performance information during Sport and Exercise, the **SOMNOwatch**® can be worn on the arm, leg, or body. Additionally, the **SOMNOwatch**® can measure ECG. The software synchronizes Heart Rate with Motor Activity. The correlation of Motor Activity and Cardiovascular Stress is very important for optimising and monitoring exercise and rehabilitation progress.
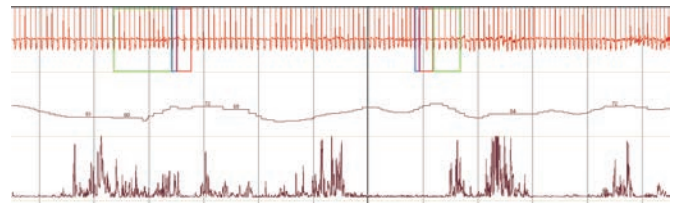
PLM and RLS Recorder

Applied to the ankle, **SOMNOwatch**® can record Leg Movement continuously for up to 5 nights. It can differentiate between standing and lying using the integrated position sensor. With adjustable parameters, the software automatically recognises PLM movement patterns and evaluates the PLM index. By quantification of Motor Activity, RLS (Restless Legs) is rated. For an extended diagnosis, the EEG option can be added to provide EEG Derivation which can be used to provide the correlation of PLM's and Cortical Micro Arousals.
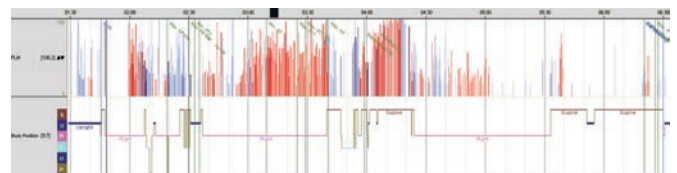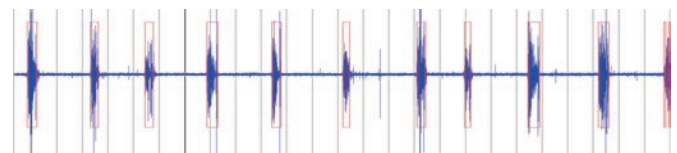
Periodic Leg Movement (PLM)

	Sleep	REM	Non-REM	Wake	Total
Isolated-LMs (Index)	189 (45,0)	-	189 (45,0)	31 (544,5)	220 (51,7)
PLMs (Index)	235 (56,0)	-	235 (56,0)	22 (386,4)	257 (60,4)
Resp-LMs (Index)	14 (3,3)	-	14 (3,3)	1 (17,6)	15 (3,5)
Body Position -LMs (Index)	13 (3,1)	-	13 (3,1)	-	14 (3,3)
PLMs with Micro Arausal	58 (13,8)	-	58 (13,8)	3 (52,7)	61 (14,3)

PLM Progression

Time	PLM	
01:45 - 02:00	2 (8,32)	
02:00 - 03:00	46 (46,00)	
03:00 - 04:00	113 (113,00)	
04:00 - 05:00	63 (63,00)	
05:00 - 06:00	8 (8,00)	
06:00 - 06:29	3 (6,02)	
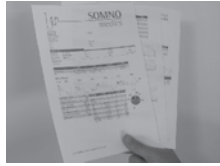
Movement Analyser

The high frequency acquisition of movement enables **SOMNOwatch®** to make a very accurate frequency analysis using FFT. The rec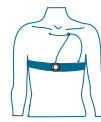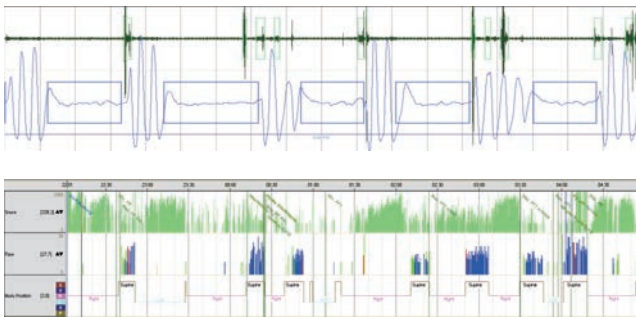ording of tremor intensity and tremor frequency can be achieved over a long period of time. This parameter can be used for the medical diagnosis and treatment of Parkinson's Disease.
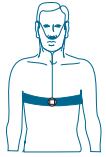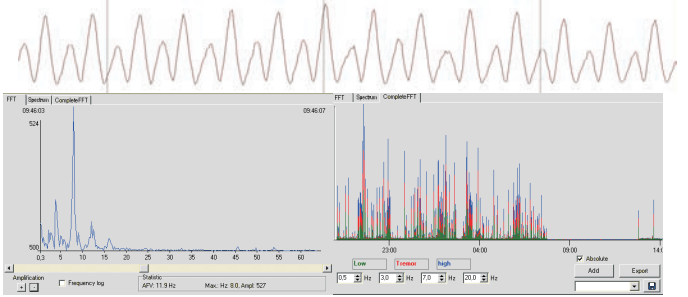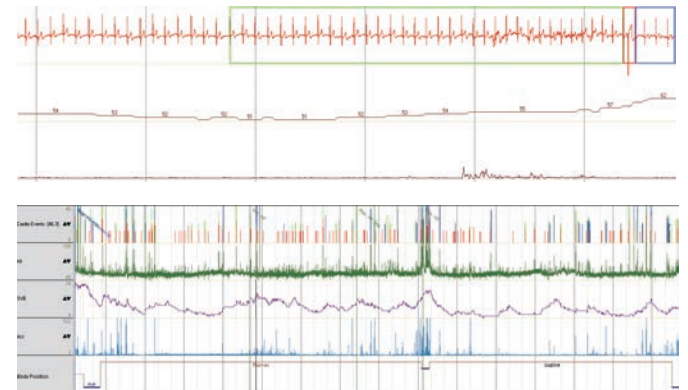
Respiratory Screener

By using a combined sensor for Flow and Snore, the **SOMNOwatch®** can be used as a Respiratory Screener. Worn on the thorax, it can record Body Position, Acceleration, Light, Flow, and Snoring. The correlation of Body Position, Apnoea/Hypopnoea and Snoring can easily be detected. In addition to the diagnosis of Sleep Apnoea, the **SOMNOwatch®** can be used for recording patients connected to a CPAP machine.

Respiratory Analysis

Body Position	Prone	Supine	Left	Right	Upright
Sleep Time Fraction (%)	-	27,5	17,2	55,3	-
Total Events (Index)	-	171 (90,1)	7 (5,9)	13 (3,4)	-
Obstr. Apnoea (Index)	-	9 (4,7)	-	-	-
Central Apnoea (Index)	-	2 (1,1)	-	-	-
Mixed Apnoea (Index)	-	-	-	-	-
Hypopnoea (Index)	-	31 (16,3)	5 (4,2)	10 (2,6)	-
Flow Limitations (Index)	-	-	-	-	-

Snore

	All	Prone	Supine	Left	Right	Upright
Snore (Index)	2335 (338,3)	-	387 (204,0)	328 (276,5)	1620 (424,2)	-
Absolute Snore (min)	42,1	-	5,4	6,2	30,5	-
Snore Episodes (min)	164,8	-	16,1	26,6	122,2	-

Snore epis. (% Sleep Time) 39,8

Long-term ECG

SOMNOwatch® can store the raw data of a single channel ECG for up to 18 hours. The correlation between Heart Rate, its Rhythm, Actigraphy and Body Position gives very interesting information for the diagnosis and rehabilitation of Cardiovascular disease.
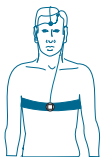
Heart rate

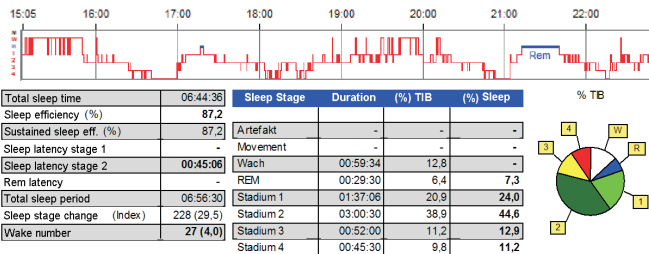|	Number(Index)	Time
Acc. (Index)	77 (10,0)	
Dec. (Index)	59 (7,6)	
Arrhythmia (index)	230 (29,7)	
Maximum Hf (bpm)	130	15:06:00
Minimum Hf (bpm)	45	17:42:13
Average Hf (bpm)	51	

Sleep Recorder

In order to differentiate the sleep stages, the EEG option can be added to the Actigraphy of the **SOMNOwatch®**. The additional data allows for the differentiation of not only the Sleep/Wake Profile but also Wake, REM, 1, 2, 3 and Stage 4.

Sleep Stages

Total sleep time	06:44:36
Sleep efficiency (%)	87,2
Sustained sleep eff. (%)	87,2
Sleep latency stage 1	-
Sleep latency stage 2	00:45:06
Rem latency	-
Total sleep period	06:56:30
Sleep stage change (Index)	228 (29,5)
Wake number (Index)	27 (4,0)

Sleep Stage	Duration	(%) TIB	(%) Sleep
Artefakt	-	-	-
Movement	-	-	-
Wach	00:59:34	12,8	-
REM	00:29:30	6,4	7,3
Stadium 1	01:37:06	20,9	24,0
Stadium 2	03:00:30	38,9	44,6
Stadium 3	00:52:00	11,2	12,9
Stadium 4	00:45:30	9,8	11,2

Long-term EEG

With very little effort, the **SOMNOwatch®** can record a single channel EEG for up to 18 hours. The artefact identification is improved by the simultaneous measurement of Motor Activity. For an optimized analysis, the raw data is represented in the different EEG frequency bands. Spindles, K-complexes, and Micro Arousals are automatically scored.
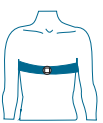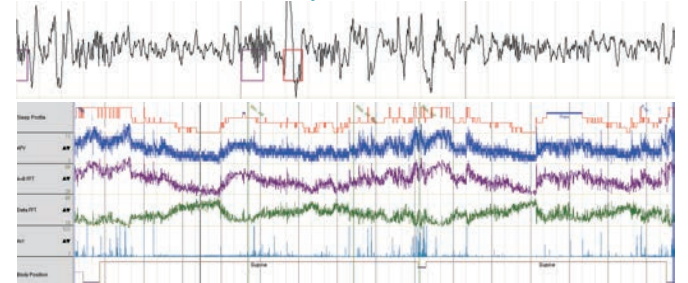
Sleep Walking

SOMNOwatch® is an excellent device for detecting this sleep disorder, as up to 14 days of Body Position, Light, and Motor Activity can be recorded. The report discriminates between lying left, right, supine, prone, upright and walking.

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LED Status Indicator

Patient Marker

Light Sensor

SOMNOwatch plus®

**External
Signal Input (AUX)
Interface/Charge**

7 Channels

6 Internal (Body Position, 3 Activity Sensors (x,y,z - Axis),
      Ambient Light, Patient Marker)

1 External Signal Input (AUX)

SENSORS FOR AUX

External Sensors	Pressure Sensor for Nasal (Oral) Flow + Snore
	Pressure Sensor for CPAP (0 to 15 cm H_2O)
	EEG Electrode
	ECG Electrode
	PLM Electrode (EMG/ACTI)

DATA PROCESSING

12 Bit ADC

Adjustable Sampling Rates - 128/s to 1/s

Adjustable Storage Rates - 1/120s to 128/s

Internal Data Storage 8/16 MB

Storage of Raw or Averaged Data User Selectable

POWERSUPPLY

Li-Ion Battery, 630 mAh (rechargeable)

SIZE & WEIGHT

45 mm Diameter x 16 mm, 30 g (incl. Battery)

DEVICE FEATURES

Battery Charging During Data Transfer through USB Port

Programmable Start- and End-Times
up to 20 Measurements

Device Status Indicator (Transferring, Recording, Standby)

Patient Marker Button

Waterproof

SOFTWARE

Fast and Accurate Analysis and Scoring Software for:

    Respiratory Analysis, PLM-Detection, Sleep, Wake, REM,
    Stage 1, 2, 3, 4, Tremor Analysis, EEG, Cardio Analysis

Editing of Events in the Raw Data

Computer aided Artefact Detection

Automatic Report and Form Letters

Data Base (Option - Compatible with SOMNOscreeen®)

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Analysis

■ Analysis of All Standard Signals

Actigraphy
Sleep/Wake Detection and Sleep Efficiency (Time-in-Bed)
Daily or Weekly Data Display
REM/NREM Differentiation (ECG Option)
REM, 1, 2, 3 and Stage 4 Differentiation (EEG Option)

PLM
Computer aided Identification of PLM & LM Correlated to Body Position
PLM-Index Distribution
Quantification of the Motor Activity for RLS
Correlation of Cortical Micro Arousals (EEG Option)

Respiratory Screener
Apnoea/Hypopnoea Detection
Snore Detection
Body Position Correlation

EEG
1-Channel EEG, up to 18 Hours
FFT Module for Sequential Frequency Analysis of the Raw Data
Spectral Analysis of Alpha, Beta, Delta and the
        Averaged Frequency Value (AVF)
Micro Arousal Analysis According to the ASDA-Criteria
Sleep Fragmentation
Artefact Detection

ECG
1-Channel ECG, up to 18 Hours
Recognition of Brady/Tachycardia and Arrhythmia
Heart Rate Variability (HRV)
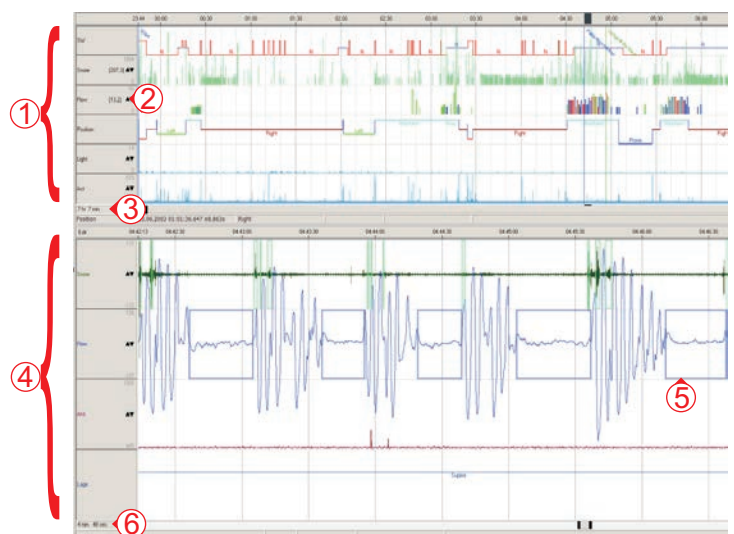Sympatho-Vagal Balance (SVB)

Tremor Analysis
Identification of Tremor Frequency & Tremor Intensity
Motion Efficiency

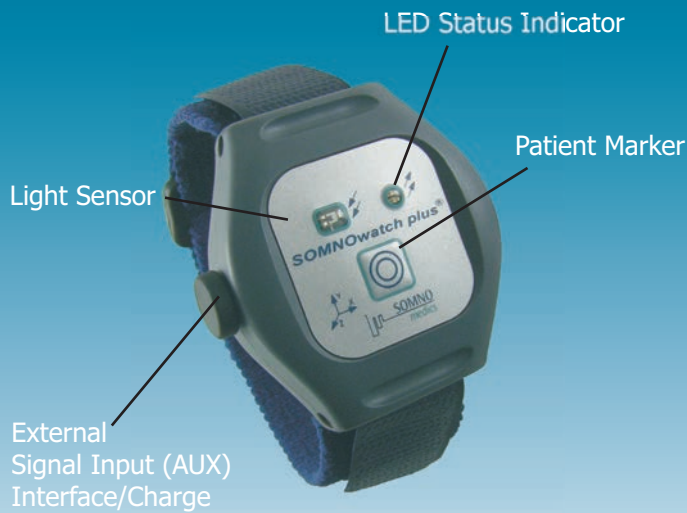### Actigraphy (Exercise, Sport, Rehabilitation)
Evaluation of Exercise Periods
Correlation of the Motor Activity and the Heart Frequency

■ Example of Respiratory Analysis

(1) Analysis Data   **(2) Index per Hour**
(3) Analysis Time-Base Data   **(4) Raw Data**
(5) Events   **(6) Raw Data Time-Base**

The system provides fully quick and easy manual editing. All events are colour coded and displayed in the Raw Data View.

Application/Configuration

	Actigraphy Sleep/Wake	Actigraphy Training/Sport	PLM Recorder	Movement Analyser	Respiratory Screener	REM/NR Recorder	Long-term Body Position	Long-term ECG	Long-term EEG
	Non-Dominant Arm	Arm - Leg Body	Leg	Arm - Leg	Thorax	Thorax	Thorax	Thorax	Thorax
Internal Body Position	●*)	●	●	●	●	●	●	●	●
Movement	●1)	●	●1)	●2)	●1)	●1)	●1)	●1)	—
Ambient Light	●	●	●	●	●	●	●	●	●
Button Marker	●	●	●	●	●	●	●	●	●
External Flow & Snore	○	○	○	○	●	—	○	—	—
ECG	○	○	○	○	—	●	○	●	—
EEG	○	○	○	○	—	—	○	—	●
CPAP	○	○	○	○	—	—	○	—	—
PLM - EMG or ACTI	○	○	○	○	—	—	○	—	—

● Standard ○ Option ●*) Position ●1) Quantitative Recording ●2) x, y, z - Axis

Flow and Snoring Sensor

PLM Sensors EMG/ACTI

SOMNOwatch plus®

EEG Sensor

ECG Sensor

7 Channels

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